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Docket No.: 3691-0123PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Koji SODE

Application No.: 10/549,703

Confirmation No.: 2203

Filed: September 19, 2005

Art Unit: 1632

For: FRUCTOSYLAMINE OXIDASE

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on September 19, 2005, attached hereto is an English Translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: November 14, 2006

Respectfully submitted,

By 

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Attachment: IPER Report

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

TANAKA, Reiko
Ohno & Partners
Kasumigaseki Building 36F
2-5, Kasumigaseki 3-chome
Chiyoda-ku, Tokyo 100-6036
JAPON



Date of mailing (day/month/year) 02 March 2006 (02.03.2006)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference PSD-9012WO	
International application No. PCT/JP2004/003587	International filing date (day/month/year) 17 March 2004 (17.03.2004)
Applicant SODE, Koji	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 70 10

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PSD-9012WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2004/003587	International filing date (<i>day/month/year</i>) 17 March 2004 (17.03.2004)	Priority date (<i>day/month/year</i>) 17 March 2003 (17.03.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SODE, Koji		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.
3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input checked="" type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Date of issuance of this report 21 February 2006 (21.02.2006)
	Authorized officer Masashi Honda Telephone No. +41 22 338 70 10

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

Translation

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

PSD-9012WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/003587

International filing date (day/month/year)

17.03.2004

Priority date (day/month/year)

17.03.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

SODE, Koji

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/003587

Box No. 1 Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☒ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☒ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/003587

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

The common matter of claims 1-10, 24, and 25, and claims 11-23 is fructosylamine oxidase.

The results of the search revealed that a document (Sode K. et al., Screening and characterization of fructosyl-valine-utilizing marine microorganisms, Mar. Biotechnol., 2001, Vol. 3, pages 126-32) describes this fructosylamine oxidase, and therefore this enzyme is not novel.

As a result, fructosylamine oxidase does not go beyond the scope of prior art, and this common matter cannot serve as a special feature in the sense of PCT Rule 13.2 (2).

Consequently, there is no matter common to all the claims.

Because no other common matter exists that can be considered a special technical feature in the sense of PCT Rule 13.2 (2), no technical association in the sense of PCT Rule 13 can be found between these different inventions.

Therefore, it is clear that the inventions of claims 1-10, 24 and 25 and the inventions of claims 11-23 do not satisfy the requirement for unity of invention.

4. Consequently, this opinion has been established in respect of the following parts of the international application:
- ☒ all parts
 - ☐ the parts relating to claims Nos. _____

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/003587

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
1. Statement				
Novelty (N)	Claims	5-9		YES
	Claims	1-4, 10-25		NO
Inventive step (IS)	Claims			YES
	Claims	1-25		NO
Industrial applicability (IA)	Claims	1-25		YES
	Claims			NO
2. Citations and explanations:				
<p>Document 1: Mar. Biotechnol., 2001, Vol. 3, No. 2, pages 126-32</p> <p>Document 2: JP 2000-270855 A (Koji SODE) 3 October 2000</p> <p>Document 3: JP 2001-204494 A (Koji SODE) 31 July 2001</p>				
<ul style="list-style-type: none"> • Claims 1-4 and 10-25 <p>Based on the descriptions in documents 1 and 2 cited in the international search report, the inventions of claims 1-4 and 10-25 lack novelty.</p> <p>Documents 1 and 2 describe a fructosylamine oxidase enzyme isolated from the N1-1 strain of <i>Pichia</i> sp., a method for assaying fructosylamine compounds such as fructosyl-valine, etc., using that enzyme, an assay method for HbA1 using that enzyme, and an enzyme sensor using that enzyme.</p> <p>Based on the description in document 3 cited in the international search report, the inventions of claims 11-25 lack novelty.</p> <p>Document 3 describes an assay method for fructosylamine compounds such as fructosyl-valine, etc., that uses fructosylamine oxidase isolated from strain N1-1 of <i>Pichia</i> sp., an assay method for HbA1 using that enzyme, and an enzyme sensor using that enzyme.</p>				
<ul style="list-style-type: none"> • Claims 5-9 <p>Based on the descriptions in documents 1 and 2 cited in the international search report, the inventions of claims 5-9 lack an inventive step.</p> <p>This examination finds that, concerning claims 5-9, persons skilled in the art can easily conceive of analyzing the amino acid sequence of the N-terminus, etc., of fructosylamine oxidase; perform screening of a DNA library prepared from microorganisms that are the origin of that enzyme by using a probe or primer prepared based on the above results; obtain DNA encoding that enzyme; incorporate that DNA into a vector; transform a host using that vector; and express the fructosylamine oxidase enzyme.</p>				